DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other than Full and Open Competition

1. **Contracting Activity:** Department of Veterans Affairs, VHA NCO 21 for VISN 21, Palo Alto Health Care System, requests approval of a Justification for Other Than Full and Open Competition for the requirement specified in 640-13-2-032-0086

2. **Nature and/or Description of the Action Being Processed:**
This action limits competition for the acquisition of the Medtronic CoreValve (a prosthetic aortic valve replacement device) for the VA Palo Alto Health Care System. This device is FDA-approved, for investigational use only, and will be used in a clinical trial. NCO 21 intends to award a new firm-fixed price contract to obtain these devices.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:**
The VAPAHCS requires an estimated 15 Medtronic CoreValve (prosthetic aortic valve replacement) devices to participate in a clinical trial.

   This one-time purchase is estimated to cost [redacted]

4. **Statutory Authority Permitting Other than Full and Open Competition:** *41 USC §253(c)(1), as implemented by FAR 6.302-2:*
   (X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;

5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):**
The authority cited in paragraph 4 must be used because the VAPAHCS has been invited to participate in several clinical trial for the Corevalve device. The device listed in paragraph 3 is the only device approved for use and is integral to participate in these clinical trials. No other devices will meet the Government's needs to participate is this trial.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:**
This requirement will be synopsized in the GPE as required by FAR 5.201.

   The synopsis will allow other offerors to respond; however, it is not likely since no other devices of this kind exist. In addition, no competition among distributors is expected.

   Specifically, the Vendor has several patents pending for these devices (20120143316, 20120083878, 20110301692, 20110213461, 20110172765, 20110125257, 20100292785, and 20100036485.

Should the United States Patent and Trademark Office grant these patents, Medtronic would have 20 years to produce those items as part of a state-granted monopoly. After 20 year, other firms would be able to produce items based on the Corevalve. It is also possible that a firm will develop a similar, but legally distinct device that would also allow for additional sources.

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:**
The Contracting Officer has determined that the anticipated price will be determined to be fair and reasonable. A Price Negotiation Memorandum (PNM) will detail how the Government has determined that the anticipated costs will be fair and reasonable.

   As this item has been determined to be commercial, cost or pricing data will not be required. Pricing techniques such as are described in FAR 13.106-3(2), will be used to establish price fairness and reasonableness.

8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:**
The VA consulted two subject matter experts: [redacted] and [redacted] The VA reviewed the previous order: VA640-A10276. The VA searched the patent office, www.clinicaltrials.gov, and vetbiz.

   Market Research indicates that only Medtronic is able to provide a device allowed to participate in the clinical trial. Medtronic is an other than small business.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:**

   The VAPAHCS is in a unique position to participate in this clinical trial. It allows the VA to use the most cutting edge and innovative medical technology. Not participating in this trial could cause harm to the Government by preventing the VA from utilizing new medical technologies.

10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:**
Medtronic Vascular, Inc.
Clincial Contracts & Alliance Management
3576 Unocal Place
Santa Rosa, CA 95406
707-597-2834

    See Section VI above.

11. **A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:**
If the clinical trial is successful, then the device will be a closer to being FDA approved for medical use. In the event it is approved, the likelihood of a competing device is low in the short term. However, the VA will be able to compete future requirements (without a clinical trial restriction) as

a brand name or equal. This action will allow other contractors to submit an offer if they can provide a viable substitute after the patent expires.

12. **Requirements Certification:** I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

[redacted]

Name: [redacted]
Title:
VA Palo Alto HCS

8 April 2013
Date

13. **Approvals in accordance with FAR 6.304**

a. **Contracting Officer's Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

[redacted]

DANIEL E. CZECH
Contracting Officer
NCO 21

4/8/2013
Date

b. **NCM/PCM (Required $3K and above):** I certify the justification meets requirements for other than full and open competition.

[redacted]

DON NEAL,
Supply Team Manager, NCO 21

4/8/13
Date